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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

SURGICAL INSTRUMENT SERVICE COMPANY, INC.,

Plaintiff/ Counterclaim-Defendant,

vs.

INTUITIVE SURGICAL, INC.,

Defendant/ Counterclaim-Plaintiff.

Case No.: 3:21-cv-03496-VC

MOTION OF INTUITIVE SURGICAL, INC. TO EXCLUDE TESTIMONY OF DR. AMANDEEP MAHAL

Hearing Date: June 8, 2023
Hearing Time: 1:00 p.m.
Hearing Place: Courtroom 4

Judge: The Honorable Vince Chhabria

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NOTICE OF MOTION AND MOTION

TO ALL PARTIES AND THEIR COUNSEL OF RECORD:

PLEASE TAKE NOTICE that on June 8, 2023, at 1:00 p.m., or as soon thereafter as available, in the courtroom of the Honorable Vince G. Chhabria, located at 450 Golden Gate Avenue, Courtroom 4, 17th Floor, San Francisco, CA 94102, Defendant Intuitive Surgical, Inc. ("Intuitive") will and hereby does move for an order excluding certain testimony of Dr. Amandeep Mahal, who is proffered by Plaintiff Surgical Instrument Service Company, Inc. ("SIS") as an expert witness.

This Motion is based on this Notice of Motion, the Memorandum of Points and Authorities, the accompanying Declaration of Cortlin Lannin and attached exhibits, any reply or other supplemental briefing and/or evidence submitted, and the oral argument of counsel.

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION AND STATEMENT OF ISSUE

Intuitive moves pursuant to Rule 702 of the Federal Rules of Evidence to exclude certain opinions of Dr. Amandeep Mahal, an expert witness proffered by SIS to opine on various topics. As set forth below, several of Dr. Mahal's opinions are beyond the scope of his surgical expertise, while others lack the threshold reliability required under *Daubert* and its progeny. The Court should exclude these opinions.

First, Dr. Mahal opines that the EndoWrist "use counter"—the term he uses for the mechanism in the EndoWrist that disables the device after its approved number of uses—"does not provide relevant information about actual use and is of no value in assessing likely instrument performance." He asserts that the "use counter" should account for several real-world factors, but he offers no basis for this opinion and fails to consider and account for extensive record evidence that Intuitive *did* consider such factors when developing the use limits, including life tests that modeled real-world conditions. Because he disregards this scientific evidence in favor of his own uninformed speculation, Dr. Mahal's opinions as to the "use counter" should be excluded.

Second, Dr. Mahal opines that "there is no reason to believe that an EndoWrist instrument that has been serviced after expiration of the Intuitive-specified use counter would not operate in the same manner as an EndoWrist whose use counter has not expired." This opinion rests only on Dr. Mahal's

hazy recollection of reviewing unidentified "documents" about the "service" process—documents that Dr. Mahal concedes he is not qualified to interpret. Dr. Mahal's admission that he has *never used* a "serviced" EndoWrist beyond its use limit only highlights the unreliability of this opinion.

Third, Dr. Mahal opines that hospitals need da Vinci systems, including to attract patients who are "keeping up with current trends." However, Dr. Mahal has neither the credentials nor experience to support these opinions.

Fourth, Dr. Mahal—who acknowledges he is a "surgical subspecialist and would never claim to be a general surgeon"—nonetheless offers a series of sweeping opinions as to how "surgeons" view different surgical modalities and choose among them. He has no basis to speak on behalf of surgeons generally.

Finally, Dr. Mahal opines as to how the da Vinci Si and Xi systems and instruments perform similarly "for most surgeries." But Dr. Mahal does not perform "most surgeries," and he identifies no other basis to support this opinion either.[1]

II. STATEMENT OF FACTS

Dr. Mahal is an obstetrician and gynecologist, as well as a board-certified female pelvic medicine and reconstructive surgeon. Lannin Dec. Ex. 1 ¶ 1. He employs both "traditional (open) and laparoscopic surgical techniques" in his practice. *Id.* ¶ 4. Dr. Mahal claims to have extensive experience using the da Vinci surgical system. *Id.* ¶ 5.

Dr. Mahal offers a variety of opinions, not all of which are the subject of this motion. Rather, this motion focuses on those of his opinions that he is unqualified to make and/or that lack any proper scientific or other reliable support in the record. This includes his opinions regarding:

- The EndoWrist "use counter," which he opines "does not provide relevant information about actual use, and is of no value in assessing likely instrument performance," and related opinions. *See* Lannin Dec. Ex. 1 ¶¶ 21, 63–66, 73; *id.* Ex. 2 ¶ 6(h).

[1] For the avoidance of doubt, Intuitive reserves its right to raise additional objections to Dr. Mahal's testimony at a later date. This brief focuses on key issues fit for resolution at this stage of the case.

- "Serviced" EndoWrist instruments—*i.e.*, EndoWrists that have been modified to reset their use counters so that they can operate past their approved live span—including his opinion that "there is no reason to believe that an EndoWrist instrument that has been serviced after expiration of the Intuitive-specified use counter would not operate in the same manner as an EndoWrist whose use counter has not expired." *See id.* Ex. 1 ¶ 62; *see also id.* ¶¶ 53–61; *id.* Ex. 2 ¶¶ 6(i)–(j).
- The business implications for hospitals of having a da Vinci system. *See id.* Ex. 1 ¶¶ 30, 36–37, 41.
- Surgeons' views of and preferences for different surgical modalities. *See id.* Ex. 1 ¶¶ 16, 33–34, 37, 39–40; *id.* Ex. 2 ¶ 6(c).
- How the da Vinci Si and Xi systems perform for "most surgeries." *See id.* Ex. 1 ¶¶ 17–18, 42–44, 51–52; *id.* Ex. 2 ¶¶ 6(d)–(e).

III. ARGUMENT

Expert witness testimony must (1) come from a qualified expert; (2) be helpful to the factfinder; (3) be based on sufficient facts or data; (4) use reliable principles and methods; and (5) reliably apply those principles and methods to the facts of the case. Fed. R. Evid. 702. The court's "gatekeeping" role requires evaluating both the reliability of the expert's methods and the connection between their conclusions and the facts on which those conclusions are based. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). To evaluate an expert's qualifications, courts look to the "expert's knowledge, skill, experience, training, and education in the subject matter of his asserted expertise." *United States v. Hankey*, 203 F.3d 1160, 1168 (9th Cir. 2000). The party proffering expert testimony has the burden of proving admissibility. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 592 n.10 (1993).

A. Dr. Mahal's Opinions That EndoWrist Use Counters Do Not Provide Relevant Information Lack a Sufficient Factual Basis and Are Unreliable.

Dr. Mahal opines that the "EndoWrist use counter does not provide relevant information about actual use, and is of no value in assessing likely instrument performance." Lannin Dec. Ex. 1 § IX; *see also id.* ¶¶ 21, 65 ("The use counter of an EndoWrist instrument does not provide a surgeon any practical, relevant information about the instrument's actual usage, whether in a particular surgery or over the life of the instrument."); *id.* Ex. 1 ¶ 73 ("… the usage counter to my understanding does not actually measure any qualitative information about actual instrument usage"); *id.* Ex. 2 ¶ 6(h). He opines that the types of "relevant information" the use counter should but does not reflect include "how

long the EndoWrist was used in surgery, how it was used, the number of particular movements, … types of movement, … types of procedures in which the EndoWrist was used, the forces it experienced, whether it malfunctioned, [] whether it was misused or abused," and "extreme use cases." *Id.* Ex. 1 ¶¶ 65–66.

To start with, these opinions appear to be based on the incorrect premise that an EndoWrist use counter is designed to convey information to the surgeon. In fact, the use counter is simply the mechanism in the EndoWrist that disables the device after its approved number of uses or "lives." *See id.* Ex. 4 ¶ 62. So if Dr. Mahal is criticizing the use counter for not communicating adequately information it is not designed to communicate at all, his opinions are irrelevant.

If, on the other hand, what Dr. Mahal intends to assert is that the use limits themselves do not reflect "relevant" information and are therefore of "no value," that opinion rests on nothing but speculation. Dr. Mahal cites no record evidence in support of his opinions about what the use limits do and do not take into account, and he fails to cite or take account of *any* of the voluminous evidence that does exist on how the use limits were developed, the testing on which they rely, and how the FDA cleared them.

For example, Intuitive's expert Dr. Robert Howe describes in detail the process Intuitive used to develop the EndoWrist use limits. *See id.* Ex. 4 ¶¶ 50–70. He notes that "[t]o verify that the design of EndoWrist instruments meets the proposed number of surgical uses, Intuitive conducts life tests," *id.* ¶ 63, and describes in detail the nature, design, results, and documentation of that testing. *See id.* ¶¶ 63–70. Notably, that includes testing the instruments in "simulated surgical procedures" that "replicate how the instrument is used in an applicable laparoscopic surgical operation." *Id.* ¶ 67. For example, certain instruments are tested for "wrist circles (moving the instrument tip in a circular pattern), needle throws (driving the needle through a single stitch), suture pulls, tissue lifts, and tissue pushes" in both animal tissue and synthetic models, and "[m]aneuvers are done in an order that replicates typical surgical usage

and repeated a specific number of times that conservatively approximates repetitions in surgery." *Id.*[2] Relatedly, Intuitive's expert Christy Foreman describes the process by which the FDA cleared Intuitive's regulatory submissions for the da Vinci system, which included the testing data supporting EndoWrist use limits. *See id.* Ex. 5 ¶¶ 75–101.

In short, Dr. Mahal's accusation that the EndoWrist use limits are "of no value in assessing likely instrument performance" because they do not account for real-world factors is flatly inconsistent with record evidence Dr. Mahal did not review that shows they do exactly that.[3] At deposition, he claimed he was "aware" that Intuitive had tested the EndoWrist beyond ten uses, but then candidly admitted "I am sure that I've never seen that data through my work with this case or elsewhere as far as like training or exercising devices to a fatigue or a failure point." *Id.* Ex. 3 at 110:3–10. He then claimed that he "asked to see what kind of testing was performed by Intuitive," and "was given information" that is cited in his report—but he was unable to substantially identify or otherwise elaborate on that "information." *Id.* at 110:11–22. Nor would Dr. Mahal be qualified to interpret any such data; he acknowledged that he is "not an expert in the testing and failure testing" or the "statistics that go along with that." *Id.* at 110:23–111:3.

Whether viewed as an issue of sufficiency or reliability under Rule 702, Dr. Mahal's unsupported speculation that the EndoWrist use limits do not account for real-world factors, and his failure to consider evidence to the contrary, requires the exclusion of these opinions. *See* Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 6268 Subdivision (b) (2d ed. 2022)

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[2] *See also* Lannin Dec. Ex. 4 ¶ 68 ("By defining a simulated surgical procedure based on observed maneuvers used in applicable laparoscopic surgeries, using animal tissue or synthetic models to emulate forces used in surgical procedures, performing maneuvers in an order replicating typical surgical usage and employing a conservative approximation of the number of maneuvers to be performed during an applicable laparoscopic surgical operation, Intuitive tests instruments in a way that helps ensure the instruments operate reliably and safely over their programmed number of instrument uses.").

[3] It is also inconsistent with his own testimony that he "never noticed any difference in the operation or failure rate of different EndoWrist instruments of the same type," which indicates the EndoWrist use limits are performing *exactly* the function for which they are intended—to ensure each EndoWrist works with equal reliability during its approved life span. *See* Lannin Dec. Ex. 1 ¶ 62.

(where an expert "'cherry picks' favorable data … but ignores a significant quantity of other important facts, the trial court would be justified in concluding that the expert's testimony is not based on sufficient facts or data"); *In re Bextra & Celebrex Mktg. Sales Pracs. & Prod. Liab. Litig.*, 524 F. Supp. 2d 1166, 1176, 1184 (N.D. Cal. 2007) (excluding as unreliable the testimony of expert who "cherry-pick[ed]" evidence "that support his conclusion and reject[ed] or ignor[ed] the great weight of the evidence that contradicts his conclusions"). As this Court has observed, "speculative testimony is inherently unreliable." *Dep't of Toxic Substances Control v. Technichem, Inc.*, 2016 WL 1029463, at *1 (N.D. Cal. Mar. 15, 2016) (Chhabria, J.) (citation omitted).

B. Dr. Rubach Has No Basis To Testify That "Serviced" EndoWrists Operate In the Same Manner as Original EndoWrists.

Dr. Mahal opines that "there is no reason to believe that an EndoWrist instrument that has been serviced after expiration of the Intuitive-specified use counter would not operate in the same manner as an EndoWrist whose use counter has not expired." Lannin Dec. Ex. 1 ¶ 62. Dr. Mahal's report does not elaborate what he means by "serviced" in this context, much less cite any testing or other reliable evidence that would support this opinion.[4] At deposition, Dr. Mahal suggested that he was referring to the type of "repair" offered by a third-party vendor like SIS, and testified that he had "ask[ed] to see any documentation [to] get an understanding of what would be involved in this kind of repair process." *Id.* Ex. 3 at 86:16–24. Based on that "high-level review," he came away with an impression that the process "seemed to be a reasonable way of going about the repair." *Id.* at 86:25–87:15. But Dr. Mahal conceded that his goal "was not to understand every piece or aspect of the repair process." *Id.* at 89:11–90:1.

To begin with, it appears that Dr. Mahal offered this opinion with little or no understanding of the specific context in which plaintiffs seek to use his opinion in this case. This case is not about

[4] Dr. Mahal acknowledges that his report "tend[s] to use the term 'serviced,' 'repaired,' 'refurbished' somewhat interchangeably," and that he was generally referring to when a hospital "send[s] out their instruments for, you know, whatever, retooling, repair, refurbish, what I mean by that is, I have said or the hospital has decided that an instrument is not functioning up to what it needs to and it needs to go out for repair work." Lannin Dec. Ex. 3 at 68:20–69:14.

"repair" of broken EndoWrists or "service" to fix instruments needing repair. Rather, it is about a process to *remanufacture* an EndoWrist (the term used by FDA) to *change* its functioning to override the use limits that are built into the device as originally manufactured. If Dr. Mahal's opinion were about "servicing" to do other things, it would be irrelevant to the issues in this case and therefore not helpful to the jury. *See Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 590 (1993) ("Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful."). If his opinion is supposed to encompass the output of SIS's remanufacturing operation, it clearly lacks foundation—he did not even appear to know what he was opining *about*.

Even crediting that Dr. Mahal reviewed "documentation" about SIS's remanufacturing process, he is not qualified to interpret that information; he conceded that he is not an "engineering expert" who could "review those papers with any kind of technical aspects." Lannin Dec. Ex. 3 at 87:12–15. Furthermore, Dr. Mahal's vague recollection of reviewing "documentation" is not a sufficient basis on which to rest his sweeping conclusion that a "serviced" EndoWrist operating beyond its original use limit would operate similarly to an original EndoWrist operating within its use limit. Indeed, Dr. Mahal conceded that ***he has never used an EndoWrist beyond its use limit***, further undermining his breezy assurance that such a device would operate in the same manner as an EndoWrist within its use limit. *Id.* at 109:22–110:1.

In addition, the handful of personal observations that Dr. Mahal *does* cite in support of this opinion are irrelevant non sequiturs. As noted in footnote 3, his observation that he "never noticed any difference in the operation or failure rate of different EndoWrist instruments of the same type" if anything confirms that the use limits work exactly as intended; he offers no explanation for how it could support his opinion otherwise. *Id.* Ex. 1 ¶ 62. In addition, Dr. Mahal claims that he is "confident" he could identify an EndoWrist that had a "substantially different response compared to typical EndoWrist instruments" or that otherwise failed. *Id.* Neither of these statements has anything to do with whether a

remanufactured EndoWrist being used beyond its use limit would operate in the same way as an original EndoWrist. As such, all of these disjointed opinions lack any reliable support and should be excluded.

C. Dr. Mahal Lacks the Expertise To Testify About the Purported Business Implications of the da Vinci System.

Dr. Mahal offers several opinions about the purported business implications for hospitals if they do or do not possess da Vinci systems. For example, he opines that "Da Vinci robotic-assisted surgery was a significant development in performing minimally invasive surgery and has become an essential 'must-have' feature for hospital and surgical center operations over the last two decades." Lannin Dec. Ex. 1 ¶ 30. According to Dr. Mahal, "there is a sense among both hospital staff and patients that an active da Vinci surgery program is a *de facto* requirement for a hospital to be up-to-date with current trends." *Id.* ¶ 41. Dr. Mahal opines that "patients consider whether hospitals are keeping up with current trends in technology and medicine when deciding on care." *Id.*

The only basis Dr. Mahal cites in his report for any of these opinions is his "conversations with patients and my general understanding from others in the profession." *Id.* At deposition, he confirmed that he has had "more and more discussion[s]" with patients about robotic surgery. *Id.* Ex. 3 at 56:17–57:7. But Dr. Mahal does not claim to be an expert in marketing or to have any job responsibilities related to it, or to have reviewed survey data or other reliable information that would support his views as to how "hospitals," "hospital staff" or "patients" generally regard the da Vinci system. This renders his opinions unreliable.

The court in the *Rebotix* action in Florida excluded certain surgeon opinions that were found to have this same failing. There, the court concluded the surgeon could not opine as what "surgeons, patients, and/or payors" thought about certain issues—in that case, reset EndoWrist instruments—where the surgeon had "not used any method to learn of the perceptions of these other groups," such as "conduct[ing] any surveys or polls" or "read[ing] any report about how other physicians felt about the repair process." *See Rebotix Repair, LLC v. Intuitive Surgical, Inc.*, 2022 WL 3226769, at *4 (M.D. Fla. Aug. 10, 2022). The same results follows here.

D. Dr. Mahal May Not Opine on Behalf of Surgeons Everywhere As to Their Preferences and Views.

Dr. Mahal offers numerous opinions on behalf of "surgeons" about their views of and preferences for different surgical modalities, including minimally invasive surgery using the da Vinci system. He states, for example, that "the numerous functional advantages of da Vinci surgery over traditional laparoscopic surgery are such that even surgeons who are capable of performing both da Vinci surgery and traditional laparoscopic surgery do not consider these two techniques interchangeable." Lannin Dec. Ex. 1 ¶ 34. According to Dr. Mahal, "experienced surgeons" like himself "also have the ability to perform traditional laparoscopic surgeries, but prefer using da Vinci systems for minimally invasive surgeries. Indeed, some surgeons have gone to offering only [robotic-assisted surgery] and would convert to open surgery if there was in issue during the procedure." *Id.* ¶ 33; *see also id.* ¶ 37 ("…many doctors find that they require a da Vinci system to consistently complete surgeries safely"); *id.* ¶ 40 ("Surgeons in fact regularly demand that a da Vinci system is made available to perform particular surgeries."); *see also id.* Ex. 2 ¶ 6(c). Relatedly, Dr. Mahal asserts that "most surgeons who perform minimally invasive surgery"—and particularly those "who entered the profession within the last 15-20 years"—"would not consider working in a facility that was not able to perform a da Vinci surgery." Lannin Dec. Ex. 1 ¶ 37.

Dr. Mahal cites no support for these sweeping opinions about surgeons' views and preferences, and he does not claim to have consulted any reliable sources that would substantiate his opinions. He has "heard" from surgeons that they require a da Vinci system to complete some procedures safely, but in his deposition he could provide no details about these alleged conversations. *Id.* Ex. 3 at 52:1–9; *see also id.* at 103:18–24 (based on his "experience" with "surgeons in the surrounding community of Omaha," "*some* of them taken to relying on the robot for most, if not all, of their surgeries") (emphasis added). In fact, Dr. Mahal acknowledged that he is a "surgical subspecialist and would never claim to be a general surgeon," further undermining his claim to speak on behalf of surgeons generally. *Id.* at 49:8–13.

Just as with his broad assertions on behalf of hospitals and patients discussed above, Dr. Mahal's unsupported opinions on behalf of surgeons should be excluded. *See Rebotix*, 2022 WL 3226769, at *4; *see, e.g.*, *Bartlett v. Mut. Pharm. Co.*, 742 F. Supp. 2d 182, 195 (D.N.H. 2010) (observing "most courts have prohibited experts from testifying … about 'what doctors generally think,' unless the testimony is based on something more reliable than simply the expert's own experience as a doctor") (collecting cases). Dr. Mahal can testify about *his own* preferences in performing surgery, but he lacks a basis to extrapolate his own views to the entire surgical profession.

E. Dr. Mahal's Opinions as to How the da Vinci Si and Xi Systems Perform for "Most Surgeries" Are Unreliable.

Dr. Mahal offers several opinions that compare the da Vinci Si and Xi systems and their instruments. For example, he opines that "for most surgeries a da Vinci Si system performs similarly to a da Vinci Xi system, provides similar advantages over traditional laparoscopic surgery, and is equally safe for patients and operation room staff." Lannin Dec. Ex. 1 ¶ 42; *see also id.* ¶ 17; *id.* Ex. 2 ¶ 6(d). In his view, the "vast majority of procedures that are performed with an Xi system and EndoWrists can be performed with an Si system and EndoWrists[.]" *Id.* Ex. 1 ¶ 52.

Dr. Mahal once again cites no evidence for these opinions, and he has no basis to opine as to how the Si and Xi systems and their instruments perform for "most surgeries" or the "vast majority of procedures." He acknowledged that he is a "surgical subspecialist and would never claim to be a general surgeon." *Id.* Ex. 3 at 49:8–13. When pressed at deposition on the basis for these opinions, he offered that it "comes from my own clinical experience with both the S, the Si, as well as the X and Xi platforms while out in independent practice," and unidentified "surgeons in the community that I spoke with." *Id.* at 108:17–109:4. That is clearly not enough to support these opinions.

Dr. Mahal also opines that "[f]rom a surgeon's perspective, corresponding Si and Xi EndoWrist instruments are equivalent" and that "[m]ost surgeons do not change procedures or surgical plans for EndoWrist usage based on whether the surgeon is using an Si system and EndoWrists or an Xi system and EndoWrists." *Id.* Ex. 1 ¶¶ 43, 51; *see also id.* ¶ 18; *id.* Ex. 2 ¶ 6(e). He cites no basis for this opinion on behalf of "most surgeons," and there is no reason to think he has one given his specialty

practice. Dr. Mahal can testify about his own experiences with the Si and Xi systems. But as with his other assertions on behalf of hospitals, patients, and surgeons, his attempt to extrapolate his own views to others should be excluded. *See Rebotix*, 2022 WL 3226769, at *4.

IV. CONCLUSION

For the foregoing reasons, the Court should grant this Motion and exclude the following of Dr. Mahal's opinions regarding:

- The EndoWrist "use counter," which he opines "does not provide relevant information about actual use, and is of no value in assessing likely instrument performance," and related opinions. *See* Lannin Dec. Ex. 1 ¶¶ 21, 63–66, 73; *id.* Ex. 2 ¶ 6(h).
- "Serviced" EndoWrist instruments—*i.e.*, EndoWrists that have been modified to reset their use counters so that they can operate past their approved live span—including his opinion that "there is no reason to believe that an EndoWrist instrument that has been serviced after expiration of the Intuitive-specified use counter would not operate in the same manner as an EndoWrist whose use counter has not expired." *See id.* Ex. 1 ¶ 62; *see also id.* ¶¶ 53–61; *id.* Ex. 2 ¶¶ 6(i)–(j).
- The business implications for hospitals of having a da Vinci system. *See id.* Ex. 1 ¶¶ 30, 36–37, 41.
- Surgeons' views of and preferences for different surgical modalities. *See id.* Ex. 1 ¶¶ 16, 33–34, 37, 39–40; *id.* Ex. 2 ¶ 6(c).
- How the da Vinci Si and Xi systems perform for "most surgeries." *See id.* Ex. 1 ¶¶ 17–18, 42–44, 51–52; *id.* Ex. 2 ¶¶ 6(d)–(e).

DATED: March 23, 2023

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